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EXAMINER

GOTTSCALK, MARTIN A

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,291

Applicant(s)

TANGELLAPALLY ET AL.

Examiner

Martin A. Gottschalk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/01/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 19-24, 32, and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 19-24, 32-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This Office Action is in response to the communication filed 05/01/2006. Claims 1-6, 19-24, 32, and 33 are pending. Claims 1-6, 19-21, 23, and 24 are amended. Claims 32 and 33 are new. Claims 7-18 and 25-31 are cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-6 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al (US Pat# 6,421,650, hereinafter Goetz) in view of Mayaud (US Pat#

5,845,255, hereinafter Mayaud), and further in view of Walker et al. (US Pat# 5,883,370, hereinafter Walker) and Brinkman et al (US Pat# 6,697,783, hereinafter Brinkman).

A. As per claim 1, Goetz discloses a method for managing healthcare data which allows a multiplicity of healthcare users to assemble a virtual healthcare clinic, the method comprising the acts of:

a) providing a central data base system capable of holding a multiplicity of health records pertaining to patients (Goetz: col 4, lns 17-21),

wherein said data base system is accessible through at least one network connection (Goetz: col 6, 22-26; col 12, lns 56-59);

b) enrolling a plurality of healthcare practitioners to create a plurality of enrolled healthcare practitioners (regarding the issue of plurality, the Examiner notes that the system of Goetz maintains a medical history of a patient, including the plurality of health care practitioners the patient uses, Goetz: col 2, lns 22-27, and that the system, "Provides a vehicles for interchange <of> data among various individuals involved in patient care such as patient, physician, pharmacist, emergency medical personnel, and hospital personnel," Goetz: col 3, lns 8-12. Thus the Examiner considers this to demonstrate that the use of the system is to be by a plurality of healthcare practitioners, including pharmacies.).

wherein enrolling a healthcare practitioner comprises

providing the healthcare practitioner with software operable on a computer system (Goetz: col 9, lns 45-49) for

reading information from medical portable access devices and writing treatment information including medical prescriptions, to said medical portable access devices and to the central database, (Goetz: col 9, lns 45-65; col 11, lns 33-39),

and

interacting with the central database over the at least one network connection (Goetz: col 6, 22-26);

c) enrolling a plurality of pharmacies to create a plurality of enrolled pharmacies (see the rejection of step b),

wherein enrolling a pharmacy comprises

providing the pharmacy with software operable on a computer system for reading healthcare information including medical prescriptions written by one of the plurality of enrolled healthcare practitioners from said medical portable access devices and reading medical prescriptions from the central database (Goetz: col 5, Ins 57-67);

d) enrolling a patient member (Goetz: col 4, section entitled "Patient Component").

The Examiner considers providing the patient component to be a form of enrolling a patient, just as enrolling healthcare practitioners in step b and pharmacies in step c involved providing those parties with software possessing pertinent functionality);

e) providing said patient member with a medical portable access device (Goetz: col 5, Ins 5-11);

f) programming said medical portable access device provided to said member with healthcare information relevant to said patient member (Goetz: col 4, Ins 50-65); and only said patient member (Goetz: col 2, Ins 52-58);

g) synchronizing the healthcare information on said medical portable access device with the healthcare information contained in said central data base (Goetz: col 3, lns 8-11; col 5, lns 50-51);

and

h) repeating acts (d), (e), (f) and (g) for a multiplicity of patient members creating a multiplicity of enrolled patient members each having a medical portable access device (See the rejection of step b regarding the multiplicity/plurality issue.),

and wherein any of the multiplicity of enrolled patient members may interact with any combination of enrolled healthcare practitioners and enrolled pharmacies (Goetz discloses use of the system with a multiplicity of providers, Goetz: col 3, lns 8-12, and recites no limitation on the number of providers a patient could interact with),

whereby by each of the multiplicity of enrolled patient member can create a virtual clinic of healthcare providers by choosing enrolled healthcare practitioners and enrolled pharmacies and presenting the portable access device provided to the member for updating at healthcare treatments and prescription fulfillment (With respect to the invention disclosed by Goetz, the Examiner considers that once

a patient possesses a "patient component" device, the patient could choose to create the claimed virtual clinic, as this would be one among the many choices the patient would have for using the device. The Examiner notes the disclosure of presenting of the device to chosen providers and pharmacists and the associated updating of treatment and prescription information, Goetz: col 5, Ins 35-62. The Examiner further considers that the invention of Goetz is intended for use by a multiplicity of individual patients.).

The following features are suggested by Goetz, but not explicitly disclosed. However these features are well known in the art as evidenced by the teachings of Mayaud.

Mayaud teaches:

- a) database used with a multiplicity of patients and their records (Mayaud: Fig 2; col 16, Ins 39-49)
- b) writing prescription information to a pharmacy directly by electronic mail and sending and receiving electronic mail (Mayaud: abstract; col 27, Ins 30-50; col 32, Ins 22-67; Fig 1, item 16),

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c) reading medical prescriptions from electronic mail (Mayaud: abstract; col 32, lns 50-53),

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Mayaud within the method of Goetz with the motivation of providing both the ability to monitor potential prescription abuse by a patient, and to enhance patient compliance with a prescribed treatment regimen (Mayaud: col 28, lns 30-37).

The following features are suggested by Goetz and Mayaud but not explicitly disclosed. However, these features are well known in the art as evidenced by the teachings of Walker:

c) reading a bar-code from a container containing a medicine and determining the identity of the medicine from the bar-code, comparing a medical the prescription with the identity of the medicine (suggested by Mayaud: col 30, lns 10-37. Walker: Figs 3 and 4; col 3, lns 19-55; col 4, lns 16-27)

and

if the identity of the medicine agrees with the medical prescription, writing a confirmation that the medical prescription has been properly dispensed to one of said medical portable access devices (suggested by Goetz: col 11, Ins 29-51. Note that the pharmacist "...verifies the authenticity of the prescription..." and then fills the prescription. The Examiner considers the subsequent filling step to include a writing step which also serves as a written confirmation; Walker: col 3, ln 18 to col 4, ln14).

It would have been obvious at the time of the invention to one of ordinary skill in the art to include the teachings of Walker with the disclosures of Goetz and Mayaud with the motivation of verifying the match between the doctor's prescription and the drug selected from the pharmacy's inventory to fill the prescription and the filled prescription container handed to the customer (Walker: col 1, Ins 39-46).

The following features are suggested by Goetz, Mayaud, and Walker, but not explicitly disclosed. However, these features are well known in the art as evidenced by the teachings of Brinkman:

transmitting a direct electronic message to the one of said plurality of enrolled healthcare practitioners who wrote the medical prescription that the medical prescription was properly filled (suggested by Goetz: col 12, Ins 1-21. The Examiner notes that the pharmacist can flag an interaction

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which is stored on the patient device, which can subsequently be read by the physician when the patient consults with the physician; see also Mayaud: col 28, Ins 22-26; col 36, Ins 16-22, note that just as an alert could go out due to an unfulfilled prescription, so could it go out when a prescription was filled. Brinkman: col 12, Ins 4-8),

and

updating the central database that the medical prescription was properly dispensed (suggested by Mayaud: Fig 17, items 55 and 57; Brinkman col 11, Ins 57-62);

B. As per claim 2 Goetz, discloses the method of claim 1 further comprising the act of

providing the multiplicity (the Examiner notes that a plurality of patients using the system of Goetz would meet this limitation.) of patient members with software operable on a computer system for reading the contents of their medical portable access device (Goetz: col 7, Ins 3-4; Fig 4), and

writing updated information on the medical portable access device (Goetz: Fig 7, note for example item labeled "SET THE TIME FOR THE NEXT DOSE FOR THE MISSED DOSE"; col 14, lns 17-19).

C. As per claim 3, Goetz discloses the method of claim 1 wherein

the multiplicity of medical personal access devices comprise smart cards (Goetz: col 4, lns 17-24; Fig 1, item 14, the Examiner notes that a plurality of patients using the system of Goetz would meet this limitation.).

D. As per claim 4, Goetz discloses the method of claim 1 further comprising

providing enrolled healthcare practitioners, and enrolled pharmacies with software functionality

wherein the healthcare information in the central database pertaining to an enrolled patient member is automatically synchronized with the portable access device whenever the enrolled member's portable access device is accessed by either

a pharmacy computer system (Goetz: col 15, ln 45 to col 16, ln 5, automatically synchronized reads on "automatically download")

or

practitioner computer which is connected to the central database during access (Goetz: col 5, lns 50-51)

whereby the central database contains a backup for the portable access devices and has up-to-date information (Goetz: col 8, lns 59 to col 9, ln 6).

E. As per claim 32, Goetz discloses the method of claim 1, wherein

a plurality healthcare practitioners are unrelated except for being enrolled (Goetz does not teach explicit relationships amongst the disclosed plurality of healthcare providers, thus the Examiner considers them to be unrelated.).

5. Claim 5, 6, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz, Mayaud, Walker, and Brinkman, as applied to claim 1 above, and further in view of Joao (US Pat# 6,283,761, hereinafter Joao).

A. As per claim 5, the combined teachings of Goetz, Mayaud, Walker, and

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Brinkman fail to explicitly disclose the features of the claim, however, these features are well known in the art as evidenced by the teachings of Joao who teaches

the method of claim 1 wherein

the plurality of enrolled healthcare practitioners comprise representatives from at least three professions chosen from the group consisting of chiropractors, optometrists, dentists, psychologists, opticians, herbalists, and podiatrists (Joao: col 12, ln 58 to col 13, ln 3).

It would have been obvious at the time of the invention to one of ordinary skill in the art to combine the teachings of Joao with the combined teachings of Goetz, Mayaud, Walker, and Brinkman with the motivation of collecting comprehensive and consistent patient information for presentation to a healthcare provider (Joao: col 1, lns 47-62).

B. As per claim 6, Goetz and Mayaud disclose the method of claim 5 further comprising

providing enrolled healthcare practitioners, and enrolled pharmacies with functionality for authenticating the identity of users (Goetz: col 2, lns 52-58, reads on “..PIN or password would be necessary...”; also col 11, lns

43-46) by a biometric measurement (Mayaud: col 9, Ins 16-27; col 10, Ins 4-10).

The motivation to combine these references is the same as provided in claim 1 for the same two references.

C. As per claim 33, Joao teaches

the method of claim 5, wherein prescriptions contain the digital signature of a healthcare practitioner (Joao: col 18, Ins 37-43).

The motivation to combine references is the same as provided for claim 5 above.

6. As per claims 19-24, they are system claims which substantially repeat the same limitations of claims 1-6 and are rejected for the same reasons provided for those claims.

Response to Arguments

7. Applicant's arguments with respect to claims 1 and 4-6 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art discloses systems and methods for constructing virtual healthcare clinics for patient use.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Thurs 8:30 -6 and alternate Fri 8:30 - 5.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MG
06/28/2006


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